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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/373,230

08/12/1999

HARUKI OKMURA

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EXAMINER

JIANG, DONG

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

08/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/373,230	Applicant(s) OKMURA ET AL.	
	Examiner DONG JIANG	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 19 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 19 and 24-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Applicant's amendment filed on 19 May 2008 is acknowledged and entered. Following the amendment, claims 20-23 are canceled, claim 18 is amended, and the new claims 24-27 are added.

Currently, claims 18, 19 and 24-27 are pending and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 20-23 are moot as the applicant has canceled the claims.

The rejection of claims 18 and 19 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18 and 19 remain rejected, and the new claims 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the last Office Action mailed on 21 February 2008, at page 2, and for the reasons below.

Applicants argument filed on 19 May 2008 has been fully considered, but is not deemed persuasive for the reasons below.

At pages 5-6 of the response, the applicant argues (regarding the limitation "one or two" in claim 26) that the new claims are not subject to this rejection, and new claim 26 is supported by the specification (page 9) because the language "one or more" must comprise "one or two" as

Art Unit: 1646

the term “more” in the claim here is equivalent to “at least two”. This argument is not persuasive because, while “one or more” may comprise “one or two”, the two phrases differ in scope. Therefore, such amendment has changed the scope of the claim, and is not supported by the original disclosure.

Further, the issue remains with claims 18 and 26, i.e., as addressed in the last Office Action, applicants have not pointed out, nor can the Examiner locate, the basis in the specification for the limitations “(i) one or more (two) amino acids ... are replaced with ..., *and* (ii) one amino acid is added to the amino acid sequence of SEQ ID NO:2”. Further, while the specification teaches “one or more amino acids are added to *the N- and C- terminals* in SEQ ID NO:2” (the paragraph bridging pages 15 and 16), it does not provide basis for the limitation “one amino acid is added to the amino acid sequence of SEQ ID NO:2” recited in claims 18 and 26, which reads on adding an amino acid anywhere in SEQ ID NO:2, not just the N- and C- terminals.

This is a new matter rejection.

Rejections under 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18 and 19 remain rejected, and the new claims 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention., for the reasons of record set forth in the previous Office Actions mailed on 8/8/07 and 2/21/08, and for the reasons below.

Applicants argument filed on 19 May 2008 has been fully considered, but is not deemed persuasive for the reasons below.

At page 7 of the response, the applicant argues that claim 26 recites “one or two” amino acid substitutions, and IFN- γ production inducing ability of the variant, which is readily assayed

Art Unit: 1646

as taught in the specification. This argument is not persuasive because claim 18 ("one or more amino acids ... are replaced", part (i)), and claim 24 ("an ... protein, excluding ... SEQ ID NO:2"), as written, still read on functional equivalents of the polypeptide of SEQ ID NO:2. The new claim 24 does not even recite any structural limitation, thus, the claim encompasses variants, without any sequence similarity to the disclosed SEQ ID NO:2. The specification merely discloses *one* IL-18 amino acid sequences with particularity, the murine IL-18 with SEQ ID NO:2, and no particular variant of the IL-18 with amino acid addition, deletion, substitution, or any other type of "functional equivalents" meeting the limitations of these claims were ever identified or particularly described. Therefore, with the exception of SEQ ID NO:2, there is no way for a skilled artisan to envision the detailed chemical structure of the encompassed variants, and therefore conception is not achieved regardless of the complexity or simplicity of the method of making a peptide or chemical molecule. Accordingly, the specification does not provide adequate written description of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016

Conclusion:

No claim is allowed.

Advisory Information:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Dong Jiang/
Primary Examiner, Art Unit 1646
8/12/08